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JUL 25 2003

Special 510(k) Summary of Safety and Effectiveness: Line Extension to the SPS Small Fragment Set and SPS Basic Fragment Set - 3.5mm and 4.5mm Periarticular Plates

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp. 59 Route 17 South Allendale, NJ 07401-1677
Contact Person:	Vivian Kelly Regulatory Affairs Consultant Phone: 201-831-5581 Fax: 201-831-6038
Date of Summary Preparation:	June 18, 2003

Device Identification

Proprietary Name:	Stryker Plating System Periarticular Plates
Common Name:	Bone Plate System
Classification Name and Reference:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR §888.3030 Smooth or Threaded Metallic Bone Fixation Fastener, 21 CFR §888.3040
Regulatory Class:	Class II

Description

This Special 510(k) submission is intended to address a line extension to the predicate SPS Small Fragment Set and SPS Basic Fragment Set which are both part of the Stryker Plating System. Both the SPS Small Fragment Set and SPS Basic Fragment Set consist of plates and screws for the fixation of fractures of the cortical and metaphyseal areas of long bones as well as fractures of the pelvis. There is no change in intended use for the modified device when compared to the previously cleared devices. The line extension involves offering a new Periarticular Plate version for the fixation of fractures of the cortical and metaphyseal regions of long bones. Howmedica Osteonics intends to add the new components to the current product line, thereby offering additional design options for the surgeon. The Periarticular Plates will be available in stainless steel (316L).

Intended Use

The Periarticular Plates are intended for use in long bone fracture fixation.

Substantial Equivalence

Equivalency of this device is based on similarities in intended use, materials, and design to other currently marketed plating systems. Analysis has been conducted demonstrating substantial equivalence to a currently marketed device.

Statement of Technological Comparison

FEA analysis demonstrates the comparable mechanical properties of the subject Periarticular Plates and predicate SPS Basic Fragment Set.

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Proposed Regulatory Class:	Class II
Device Panel/Product Code:	87 HRS: Plate, Fixation, Bone 87 HWC: Screw, Fixation, Bone

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2003

Ms. Vivian Kelly
Regulatory Affairs Consultant
Howmedica Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Re: K031959
Trade/Device Name: Stryker Plating System Periarticular Plates
Regulation Number: 21 CFR 3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: LXT
Dated: June 18, 2003
Received: June 25, 2003

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031959

Device Name: 3.5mm and 4.5mm Periarticular Plates

Indications For Use:

The 3.5mm and 4.5mm Periarticular Plate components are intended for use in long bone fracture fixation.

The 3.5mm and 4.5mm proximal tibial Periarticular Plates are indicated for fixation of long bone fractures, including, but not limited to, fractures of the tibia. The 4.5mm distal femur Periarticular Plates are indicated for fixation of long bone fractures, including, but not limited to, fractures of the femur.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General. Restorative
and Neurological Devices

510(k) Number K031959